UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,207	11/28/2007	Terence J. Colgan	MTS5USA	3654

270 7590 11/17/2009

HOWSON & HOWSON LLP
501 OFFICE CENTER DRIVE
SUITE 210
FORT WASHINGTON, PA 19034

EXAMINER	
SWITZER, JULIET CAROLINE	
ART UNIT	**PAPER NUMBER**
1634	

NOTIFICATION DATE	DELIVERY MODE
11/17/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@howsonandhowson.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,207	COLGAN ET AL.	
	Examiner	Art Unit	
	Juliet C. Switzer	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19-39,41-46,48 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-17,19-39,41-46,48 and 49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

2. The following groups are present in this application:

1. Claims 2-17 and 19-21, drawn to methods for detecting endometrial disease in a subject, classified in class 435, subclass 6 or 7.1.
2. Claims 22, 30-39, 48-49, drawn to diagnostic composition, markers and kits, classified in class 536, subclass 23.1, for example.
3. Claim 23-25, drawn to methods for testing drug efficacy, classified in class 436, subclass 501.
4. Claim 26, drawn to method for inhibiting cancer, classified in class 424, for example.
5. Claim 17, drawn to a method of assessing endometrial cancer cell carcinogenic potential of a test compound, classified in class 436, subclass 501.
6. Claims 28-29, drawn to methods for in vivo imaging of endometrial disease, classified in class 128, subclass 916.
7. Claims 41-45, drawn to methods of determining uterine endometrial receptivity, classified in class 435, subclass 6 or 7.1.
8. Claim 46, drawn to method of contraception, classified in class 424, subclass 812.

3. Claim 1, 38, and 39 link(s) inventions 1, 3, 4, 5, and 7. The restriction requirement among the linked inventions is **subject to** the nonallowance of the linking claim(s), claims 1, 38, and 39. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions **shall** be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 **Claims that require all the limitations of an allowable linking claim** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, the allowable linking claim, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions listed as Groups 1-8 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no special technical feature that joins all of the claims. A technical feature present in groups 1, 3, 4, 5, and 7 is represented in linking claim 1. However, this cannot be considered a special technical feature under PCT Rule 13.2 because this is not a contribution over the prior art. See for example, Byrjalsen et al. (WO 98/10291), as cited in IDS filed 10/9/07, who teach methods for detection of proteins which are specifically produced in the endometrium, and particularly teach comparing the level of protein in normal endometrium and sample endometrium showing hyperplasia or adenocarcinoma (abstract and claim 1 on page 54, for example). Also, the products of group 2 are not considered to join the groups because they are anticipated, for example, by Byrjalsen et al. Further, the remaining

groups are not joined by a special technical feature because they are drawn to methods which do not use common product or have common objectives.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

A. The species are as follows:

(a) methods and products where the markers are proteins

(b) methods and products where the markers are polynucleotides.

B. The species are as follows for the identity of the endometrial markers:

Applicant should elect a single group of "one or more" markers listed in Table 1, 4, 5, or 6 or that have a sequence of SEQ ID NO: 1, 3, 6, 9, 11, 13, 15, 18, 21, 23, 26, 30, 33, 36, 38, 40, 42, 45, and 47.

Applicant is required, in reply to this action, to elect a single species from (a) or (b) and a single group of markers to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following manner:

(A) Claims 3-4 are related to methods and products where the markers are proteins.
Claims 11-17 are related to methods where the markers are polynucleotides.
In claims 30-39 the markers are polypeptides.

The following claim(s) are generic to (a) or (b): 1, 2, 5-10, 19-29, 41-46, and 48-49.

(B) In claim 34, the markers are from Table 1, 4, 5 or 6
In claim 35, 36, and 37 the markers are selected from the recited SEQ ID NO. Each of these claims recites a different combinations of SEQ ID NO to choose from.
In claim 38, the markers are selected Table 1 or from the recited SEQ ID NO.
In claim 39 the marker is chaperonin 10.

The following claims(s) are generic to any combination of one or more markers: 1-17, 19-33, 41-46, and 48-49.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: For species election (A), the two different types of markers are different chemical compositions which are not joined by any special technical feature, and which are detectable using different methodologies. Markers that are polypeptides are comprised of amino acids and detected, for example, by immunoassay while markers that are nucleic acids are comprised of nucleotides and are detected, for example by hybridization assay. In the case of species election (B) each combination of markers is comprised of a set of molecules that differs from each other combination of markers by the structure of the markers as each individual marker is a unique polypeptide or nucleic acid encoding it, and combinations of these all comprise unique sets of molecules. These are not joined by any common structure that is a contribution over the prior art.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C Switzer whose telephone number is (571) 272-0753. The examiner can normally be reached on Monday or Tuesday from 8:30 AM until 5:00 PM, or on

Wednesday from 8:00 AM until 1:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached by calling (571) 272-0731.

The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-0507.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Juliet C. Switzer/
Primary Examiner
Art Unit 1634